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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/294,980	04/19/1999	J. OLIVER DOLLY	17259(AP)	6681

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	25

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

7 1 02

Office Action Summary	Application No.	Applicant(s)	
	09/294,980	DOLLY ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,11 and 13-24* is/are pending in the application.

4a) Of the above claim(s) *11,13-15 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendments filed December 17, 2002 (Paper No. 22) has been entered. Claims 1-3 have been amended.

Claims 1-6, 9, 11, and 13-24 are pending in the instant application.

Claims 11, 13-15, and 17-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper No. 15.

Claims 1-6 and 9 encompass non-elected subject matter. The elected invention is limited to preventing expression of a ciliary neurotrophic factor (CNTF) gene. Thus, Claims 1-6 and 9 are examined herein only to the extent that they encompass the elected subject matter.

Claims 1-6, 9, and 16 are examined herein.

The following rejections are reiterated and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2002 (Paper No. 22) has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1-6, 9, and 16 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-6 of the Office Action of Paper No. 18 (mailed 4/23/02) and on pages 4-5 of the Office Action of Paper No. 16 (mailed 7/19/01), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the full scope of the claimed invention. Applicants are referred to the final guidelines on written description (hereinafter referred to as the 'Written Description Guidelines') published January 5, 2001 in the Federal Register at Volume 66, Number 4, pp. 1099-1111 (also available at www.uspto.gov).

At pages 2-5 of the response, Applicants argue that they are not claiming a composition, but rather are claiming a method of accomplishing a therapeutic effect through the use of any ribozyme or antisense molecule that has the described functional characteristics. Given that the Written Description Guidelines explicitly state that "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention" (paragraph 2 at page 1105), the lack of appropriate materials for carrying out the claimed invention is properly a written description issue. In the instant case, the disclosure does not specify sufficient structure to perform the functions required by the claim. The inhibitory agent is an essential element of the claimed method and therefore must be in the possession of Applicants as of the priority date. Applicants assert that the teachings of the specification in combination with Usman et al. (1996) are

sufficient written description of an inhibitory agent. However, Usman et al. provides only general teachings relating to the development and design of ribozymes. Usman et al. does not provide any specific teachings relating to a ribozyme that would prevent expression of a CNTF. Further, a teaching of a nucleotide sequence for a CNTF cDNA is not sufficient to provide a written description of an inhibitory agent such as a ribozyme or antisense nucleic acid molecule. Neither the specification nor the prior art even points to a **target sequence** within the CNTF cDNA that would be an appropriate target for the ribozyme or antisense molecule. It is further noted that the claims encompass inhibiting CNTF expression in a wide variety of animals, and therefore have a very broad scope with regard to the various CNTF nucleic acid sequences that would be the target of the inhibitory agent. While the skilled artisan may develop a wide variety of molecules using these general guidelines, there is insufficient guidance regarding which molecules will function *in vivo* in the manner intended.

The limited information regarding the contemplated embodiments is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of agents for the inhibition of CNTF gene expression. Thus, it is concluded that the written description requirement is not satisfied for methods of using the genus of agents recited in the claims.

Enablement

Claims 1-6, 9, and 16 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 6-9 of the Office Action of Paper No. 18 (mailed 4/23/02) and on pages 5-7 of the Office Action of Paper No. 16 (mailed 7/19/01), as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pages 6-7 of the response, Applicants address the enablement rejection. Applicants' arguments are exclusively directed to the construction of ribozymes and are further particularly directed

to the construction of hammerhead ribozymes. However, the claimed methods are not limited to the use of ribozymes, but rather are directed to the use of any agent that inhibits expression of a CNTF polypeptide. While the claims encompass the use of any agent to inhibit the expression of CNTF genes, the specification only explicitly contemplates the use of antisense and ribozymes.

With regard to the construction of ribozymes for use in the claimed method, the references cited in this rejection demonstrate that the *in vivo* effects of ribozyme and antisense agents is unpredictable and the instant specification does not offer specific guidance for overcoming the problems acknowledged by those of skill in the art. Rather, the specification in combination with the prior art only offers general guidance for the design of ribozymes. Given the unpredictability of ribozyme and antisense design for *in vivo* applications, for reasons of record, the lack of working examples directed to inhibition of CNTF expression, the broad scope of the claims, and the limited guidance in the specification, undue experimentation would have been required to practice the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 remains indefinite because it encompasses non-elected inventions. A restriction requirement was set forth in Paper No. 12 (mailed 12/18/00). Applicants elected the invention of Group III, directed to a method for extending the effective time tissue is paralyzed with a clostridial toxin comprising administering agents that prevent the expression of various neurotrophic factor genes, including use of ribozymes. Claim 6 still recites a variety of other types of inhibitory agents that do not read on the elected invention.

At page 8, paragraph 4 of the response, Applicants argue that it is appropriate to retain a claim linking species even after the election of species is made. However, in the instant case, a restriction requirement was also made, and Claim 6 continues to cover the non-elected inventions of Groups I and II, as well as the elected invention (Group III).

Conclusion

No claims are allowable.

This application contains claims 11, 13-15, and 17-24 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER